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Applicant: Jaroszeski et al.
Serial No. 09/939,518
Filing Date: 08/24/2001
Practitioner's Docket No.: 1372.34

Group Art: 1635
Examiner: Jone E. Angell, Ph.D.

Please cancel claims 3, 5, 9, 13 and 19 without disclaimer to their content and without prejudice to their subsequent reintroduction into this or a future patent application.

Exhibit A attached hereto indicates how the original claims 2, 5, 11, 12, 15, 18 and 20 were amended to produce the amended claims 2, 5, 11, 12, 15, 18 and 20 submitted herewith. Added terms are underscored and deleted terms are bracketed:

REMARKS

Assignee's executed Revocation of Power of Attorney and new Power of Attorney documents are attached hereto. Applicant has carefully studied the nonfinal Examiner's Action mailed May 9, 2002 and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office. Claims 1-20 are pending in the application.

Claim Rejections - 35 U.S.C. § 112

Applicant acknowledges the quotation of 35 U.S.C. § 112.

Claims 11-20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Reconsideration and withdrawal of this ground of rejection is requested for the reasons that follow.

Claims 11, 12, 18 and 20 have been rewritten to better describe that which the applicant regards as the invention. In view of the amended claims, applicant now believes that claims 11-20 are definite with regard to the written description. Applicant describes a molecule introducer

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at pg. 7, lines 12-14 as being selected from a group consisting of a traditional syringe injector, jet injector, oral dose, or other means known in the art. Additionally, applicant describes an electric field applicator at pg. 8, lines 12-14 as four surface electrodes placed on adjacent sides of the injection site and a series of discrete electric pulses applied to the skin, and at pg. 10, lines 8-9 as a penetrating electrode inserted into the muscle tissue and electric fields applied. As such, applicant believes that the rejection of claims 11-20 have been overcome by amendment.

Claims 9 and 19 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 9 and 19 have been cancelled.

Claim Rejections - 35 U.S.C. § 102

Applicant acknowledges the quotation of 35 U.S.C. § 102.

Claims 1, 4-11 and 14-20 stand rejected under 35 U.S.C. 102(a) as anticipated by Lucas et al. (DNA and Cell Biol. Vol. 20(3):183-8; March 2001). Applicant herein traverses the reference under 37 CFR § 1.132. Accordingly, the Lucas et al. reference is not prior art under 35 U.S.C. 102(a).

Claims 1, 4-5 and 14-20 stand rejected under 35 U.S.C. 102(a) as anticipated by Heller et al. (DNA and Cell Biol. Vol. 20(1):21-6; January 2001). Applicant herein traverses the reference under 37 CFR § 1.132. Accordingly, the Heller et al. reference is not prior art under 35 U.S.C. 102(a).

Claims 1, 4-5 and 14-20 stand rejected under 35 U.S.C. 102(a) as anticipated by Betten et al. (Bioelectrochemistry Vol. 52:83-90; September 2000). Applicant herein traverses the rejection.

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The Office contends that Bettan teaches a method for facilitating a delivery of a desired molecule into a target tissue comprising a cell and applying a substantially continuous low-level electric field to the target tissue for a duration sufficient to effect a change in porosity of the cell of the target tissue sufficient to facilitate entry of a desired molecule into an interior of a cell, pg. 84, first column and pg. 89, first column.

Bettan describes a method utilizing, "pulses characterized by a low voltage-to-distance ratio and a long duration", at pg. 84. Bettan goes on further to describe the method on pg. 85, whereby, "each tumor was submitted to eight pulses of 20ms duration at a voltage-to-distance ratio ranging from 200 to 800V/cm". Bettan summarizes his method on pg. 88, wherein he describes, "using trains of eight pulses of 20ms duration." Clearly, Bettan is suggesting a series of low-level pulses to effect the delivery of the molecule into a target tissue.

By contrast, the present invention claims, "a substantially continuous low-level electric field", which is not equivalent to the "series of pulses" taught by Bettan. The present invention discloses and claims a method for facilitating the delivery of a desired molecule wherein a single low-level electric field is applied for a duration sufficient to effect the entry of the desired molecule into the cell. As such, the duration of the continuous low-level electric field is sufficiently long enough to effect the entry and a plurality of low-level pulses is not required. While the present invention does claim a plurality of low-level electric fields being applied, the duration of each low-level field applied is sufficient to effect a change in porosity of the cell of the target tissue sufficient to facilitate entry of a desired molecule into an interior of the cell.

As such, Bettan does not anticipate the use of a substantially continuous low-level electric field applied for a duration sufficient to facilitate entry of a molecule into the interior of a cell. The low-level pulse suggested by Bettan is not sufficient to effect the entry of a molecule into a cell, rather it is the series of pulses that is required.

Claims 1, 4-6, 8-11, 14-16 and 18-20 stand rejected under 35 U.S.C. 102(b) as anticipated by Mir et al. (PNAS Vol. 96:4262-4267; April 1999). Applicant herein traverses the rejection.

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Regarding independent claim 1, the Office contends that Mir teaches a method for facilitating a delivery of a desired molecule into a target tissues comprising a cell, and applying a substantially continuous low-level electric field to the target tissue for a duration sufficient to effect a change in the porosity of the cell of the target tissue sufficient to facilitate entry of a desired molecule into an interior of a cell, pg. 4262, abstract.

The Applicant agrees that Mir describes a "low-field strength (less than 300V/cm) and of a long duration (more than 1ms)". However, Mir also describes in the same sentence, "using square-wave electric pulses". As such, Mir is suggesting a series of low-level pulses, not a continuous low-level pulse of a duration sufficient to facilitate entry of a molecule into a cell. Mir goes on to describe a variety of experiments on pg. 4262, last paragraph, in which "10 pulses, 800V/cm, 4ms per pulse", "8 pulses, 250V/cm, 50ms per pulse", and "6 pulses, 200V/cm, 50ms". It is clear that Mir is suggesting the use of a series of pulses. Mir does not describe or suggest the use of a continuous low-level pulse of a duration long enough to effect entry of a molecule into a cell as claimed by the present invention.

Regarding independent claim 11, for the reasons cited above, Mir does not anticipate a system whereby a continuous low-level electric field is applied for a duration sufficient to effect the entry of a desired molecule into a cell. As such, independent claim 11 is not anticipated by Mir and is believed to be in condition for allowance.

Claims 1-20 stand rejected under 35 U.S.C. 102(b) as anticipated by Hofmann et al. (U.S. Patent 6,055,453). Applicant herein traverses the rejection.

Regarding independent claim 1, the Office contends that Hofmann teaches a method for facilitating the delivery of a desired molecule into a target tissue comprising a cell and applying a substantial continuous low-level electric field to the target tissue for a duration sufficient to effect a change in porosity of the cell of the target tissue sufficient to facilitate entry of a desired molecule into an interior of a cell, and cites col. 1, lines 6-13; col. 10, lines 3-56; and col. 11, lines 63-65.

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Applicant agrees that Hofmann describes at col. 10, lines 3-56 the application of low-level electric pulses of long duration. Hofmann further generalizes, "when the electric field is low, the pulse length is long". Hofmann also suggests a pulse length of between about 10 microseconds and about 100ms. However, the descriptions by Hofmann all suggest the use of a series of pulses to facilitate the entry of the molecule. Hofmann does not describe or suggest the use of a single low-level electric field that is applied for a duration sufficient to effect the entry of the molecule into the cell. As such, Hofmann does not anticipate independent claims 1 and 11 of the present invention.

For the reasons cited above, Applicant believes that independent claims 1 and 11 are now in condition for allowance.

Claims 2, 4-8 and 10 are dependent upon claim 1 and are therefore allowable as a matter of law.

Claims 12, 14-18 and 20 are dependent upon claim 11 and are therefore allowable as a matter of law.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

Very respectfully,

SMITH & HOPEN

By: *Molly Sauter*

Dated: October 9, 2002

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